UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/269,903	05/06/99	WATTS	P WC131

HM12/0227

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EXAMINER	
CHOI, F	
ART UNIT	**PAPER NUMBER**
1616	13

DATE MAILED: 02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/269,903	WATTS, PETER JAMES	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Examiner in consideration of Applicant's response (12/1/00) and upon review of the record withdraws the finality of the prior Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 19, 21-28 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is broadly attempting to claim a controlled release composition comprising pellets comprising an inner core comprising a drug which possesses a free acid group which can be converted into an alkali metal salt and a pKa in the range of 2-9 where the inner core is coated with a rate controlling membrane that determines drug release, the drug is present as a salt that displays higher solubility at pH 4.5-8 than the corresponding compound containing a free acid group and where the composition is adapted to prevent the release of drug until the composition reaches the terminal ileum or the colon following oral administration, a method of preparing the same, a method of improving the release profile of said drugs, and a method of treating intestinal diseases. However, the Specification appears to contain limited direction as to what components fall within the scope of

this broad claim. It appears that only tablets and capsules are disclosed as possible formulations, that only sugar or drug salt are disclosed as possible cores, that only ridogrel and similar molecules described in U.S. 4, 963,573 and sodium cromoglycate are disclosed as suitable drugs and appear to be the only drugs which are disclosed as being suitable for treatment of the disclosed intestinal diseases, and that only adaptation to prevent the release of the drug until the composition reaches the colon which appears to be disclosed is the coating itself which is limited to certain types of coating compounds. Because it appears that only limited direction is give, it appears that a skilled artisan would not immediately envisage every possible component that could fall within the scope of Applicant's broad claims.

Claims 1-17, 19, 21-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pellets, capsules and tablets, ridogrel and similar molecules described in U.S. 4, 963,573 and sodium cromoglycate and adaptation wherein the adaptation is the use of the disclosed coating compounds, a inner core formulated from a sugar sphere or drug salt, does not reasonably provide enablement for other drugs, other adaptations or cores. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As indicated above, the Specification appears to give limited direction as to the suitable components of the claimed invention. As such, it appears that a skilled artisan would be required to do undue experimentation in order to determine what other compounds have the desired characteristics of the invention, including whether a drug is thromboxane synthase A2 inhibitor or a thromboxane A2/prostaglandin endoperoxide receptor antagonist, or whether the coating compound will prevent release of the drug until it reaches the colon, or whether the

compound is suitable as core material, and what other composition forms would be suitable for a delayed release composition.

Claims 1-17, 19, 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting one or more of the following essential elements or steps, such omission amounting to a gap between the elements or steps. See MPEP § 2172.01. The omitted elements or steps are: the composition in the form of a capsule or tablet (See Claims 1-12, 14-17, 19, 22, 23), a rate controlling membrane prevents release of the drug until the composition reaches the colon which is determined by the type of coating compound, its pH solubility and thickness (See Claims 1-17, 19, 21-28), the coating of the pellet with the rate controlling membrane (See Claims 15, 16, 23), an effective amount of a drug which is effective in treating the claimed intestinal diseases (See Claim 19), .

Claims 1-17, 19, 21-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "wherein the composition is adapted to prevent release of the drug until the composition reaches the terminal ileum or the colon following oral administration of the composition" in claims 1-17, 19, 21-28 renders the claims indefinite as it is uncertain what is meant by said phrase. The phrase describes the problem but does not appear to indicate how the problem is to be solved.

Claim 6 recites "EUDRAGIT™ NE30D" which renders the claim indefinite as trademarks identify the source, i.e. the manufacturer, and not the composition or compound, which formulation is subject to change by the manufacturer.

Claim 13 recites the phrase "designed to disintegrate and release the pellets" which renders the claim indefinite as it is uncertain how the combination of polymethacrylates are designed to disintegrate and release the pellets.

Claims 15, 16, 23 contain the phrase "A method for making a composition comprising pellets . . ., the method comprising making a salt of the drug and coating the salt onto the inner cores" which renders the claim indefinite as the end result does not appear to be the pellet but an inner core coated with the drug and it is uncertain whether the language in the preamble is a required limitation, if so it should be in the body of the claim, or merely descriptive.

Claim 21 recited the term "coated" which renders the claim indefinite as it is uncertain what the tablet is coated with.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-12, 14-17, 19, 23 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Juch.

Juch expressly discloses composition and method of administration thereof comprising a pellet, which can be administered in capsules, wherein the pellet contains an inert core, sodium salt of diclofenac coated on said core, and a membrane layer containing ethylcellulose and/or methacrylates falling within the scope of applicant's claims (See Column 7, lines 30-68, Column 8, lines 1-45, Column 9, lines 12-68, Column 10-16.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC
February 22, 2001

JOHN PAK
PRIMARY EXAMINER
GROUP 1600